King, Valerie A.

From: Liang, Qiwei

Sent: Thursday, March 04, 2004 11:55 AM

To: Mendes, Paul; Zedler, Barbara; Gogova, Maria; Feng, Shixia; King, Valerie A.; Kinser, Robin D.; Sarkar, Mohamadi

Cc: Roethig, Hans

Subject: Suggestions for access to interim information from clinical studies

Dear All,

The discussion in yesterday's meeting was good. I can see that there are two possible types of request for interim information (before database lock) in our clinical studies:

1) Access for overseeing the quality of the studies

A clinical program leader or a study manager may want to see the compliance with the study protocol, the acceptability of the data, the success of the planned accrual targets and dropout rate and so on. It does not require access to information on comparative "treatment" effects. Access to "treatment" information can result in study bias.

2) Access for accruing of comparative "treatment" results

The sponsor may want to assess the progress of a clinical study such as whether an exposure reduction has shown up and make decisions on whether to continue, modify or stop a study. The information may also be used for planning new studies. It does require access to information on comparative "treatment" effects.

For 1), we can ask MDS to send us interim data listings without "treatment" information. But Clinical Operation needs to specify the data items. In 2), an interim analysis plan should be clearly specified in the clinical study protocol.

The above is a statistical perspective. I believe it is based on GCP.

Best regards,

Qiwei